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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,036	12/04/2003	Paul B. Davis	121936-40306609	4847
20583	7590	11/14/2007		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3735	
			MAIL DATE	DELIVERY MODE
			11/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,036	<b>Applicant(s)</b> DAVIS ET AL.	
	<b>Examiner</b> Samuel G. Gilbert	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-16 and 18-26 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13 and 27-39 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/2007 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1-8, 10, 12 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sony (TCD-D8 1995) in view of Girolamo et al (3,023,388, hereinafter Girolamo).

Sony teaches a device comprising a computer readable medium for storing a desired signal (as described on pages 2, 28-29 and 35), an output for outputting the signal to the auditory system, and a volume-adjusting feature (described on pages 18 and 37); wherein the device is capable of being used to treat an auditory system

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disorder, including tinnitus and hyperacusis, and wherein the patient may reset the volume at any time; wherein the device includes a compliance monitoring device (as described on page 40), a battery (as described on page 25); wherein the battery life may last for at least one week of treatment depending on the length of use of the device during the treatment (as described on page 25); wherein the computer readable medium has a storage capacity sufficient to provide a choice, range, or diversity of treatment signals (as described on pages 2, 28 and 29); wherein the computer readable medium storage capacity is approximately equivalent to 4 hours (as described on page 35); wherein the device further comprises coding of the treatment signal capable of preventing copying and tampering by a user (as described on page 29); wherein the device comprises a data downloading function, performed by a wired interface, capable of downloading logged information (for example: preferred treatment signals) which relate to the patient's use of the device (as described on page 28). Sony does not teach that the volume adjusting feature requires the user to reset the volume at the beginning of each treatment session. It is old and well known in the art of control devices to use a combined volume control and on/off switch, as shown by Girolamo. The device of Girolamo requires the user to set the volume each time the device is turned on from the off position. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a control device that requires the user to set the volume each time the device is turned on as required by the switch taught by Girolamo with the device of Sony to reduce the number of separate controls required by the device of Sony, thereby making the device easier to manufacture.

Claims **27-30, 33 and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gooch (Patent 5403262) in view of Girolamo et al (3,023,388, hereinafter Girolamo).

Gooch teaches a device comprising signal filtering means configured to generate a treatment signal with peaks and troughs (as seen in Figures 9-12), an output for outputting the signal (as seen in Figures 3 and 4), and a volume adjusting feature (as described in lines 48-64 of column 4; in lines 24-45 of column 5; and in lines 55-66 of column 7); wherein the signal filtering means filter an input signal as required to treat a user and is therefore capable of treating hyperacusis; wherein the effectiveness of the treatment signal depends on the individual patient during each peak and trough; wherein the device further comprises a compliance monitoring device which allows a specified or predetermined time interval for a given treatment session to be selected with a timer selector (as described in lines 57-63 of column 5). Gooch teaches separate on/off and volume controls and the volume is not required to be reset at the beginning of each session. It is old and well known in the art of control devices to use a combined volume control and on/off switch, as shown by Girolamo. The device of Girolamo requires the user to set the volume each time the device is turned on from the off position. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a combined control device for the on/off and volume function that requires the user to set the volume each time the device is turned on as required by the switch taught by Girolamo in place of the separate controls required by the device of Gooch, thereby making the device easier to manufacture. The computer readable

medium includes sufficient storage capacity as claimed. The stored signals may be repeated as necessary to provide 4 hours of treatment signal.

Claims **27-29, 31-34 and 37-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Adleman (Patent 6041129) in view of Girolamo et al (3,023,388, hereinafter Girolamo).

Adleman teaches a device comprising a signal filtering means configured to generate a treatment signal with peaks and troughs by modification of an input signal, an output for outputting the signal, a volume adjusting feature, a battery for supplying power to the device wherein the battery life may be equivalent to at least one week of treatment depending on the treatment regime; wherein the device further comprises a data downloading function capable of downloading logged information wherein the data downloading function is performed by a wired or wireless interface (as described in lines 41-44 of column 6, lines 62-64 of column 14; in lines 36-48 and 62-67 of column 16, and lines 1-60 of column 17). However the volume is not required to be reset at the beginning of each session. Adelman teaches separate on/off and volume controls as shown in figure 11. It is old and well known in the art of control devices to use a combined volume control and on/off switch, as shown by Girolamo. The device of Girolamo requires the user to set the volume each time the device is turned on from the off position. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a combined control device for the on/off and volume function that requires the user to set the volume each time the device is turned on as required by

the switch taught by Girolamo in place of the separate controls required by the device of Adelman, thereby making the device easier to manufacture. The computer readable medium includes sufficient storage capacity as claimed. The stored signals may be repeated as necessary to provide 4 hours of treatment signal.

Claims **27-29, 31-34 and 35-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Topholm (Patent 4947432) in view of Girolamo et al (3,023,388, hereinafter Girolamo).

Topholm teaches a device comprising a signal filtering means, an output, a volume adjusting feature capable of being used for requiring a patient to reset the volume of a treatment signal, a coding of the treatment signal and a patient identification code which serve as a locking function, and a battery which serves to supply the device with power and wherein the life of the battery may provide at least one week of treatment depending on the treatment regime (as described in lines 37-42 of column 2, lines 30-33 of column 3, lines 9-18 of column 4, lines 10-17 of column 5, and in lines 59-60 of column 6); wherein the signal filtering means filter an input signal as required to treat a user and is therefore capable of treating hyperacusis; wherein the effectiveness of the treatment signal depends on the individual patient. Separate controls for volume -16- and on/off "E/A" button are set forth. It is old and well known in the art of control devices to use a combined volume control and on/off switch, as shown by Girolamo. The device of Girolamo requires the user to set the volume each time the device is turned on from the off position. It would have been obvious to one of ordinary skill in the

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art at the time the invention was made to use a combined control device for the on/off and volume function that requires the user to set the volume each time the device is turned on as required by the switch taught by Girolamo in place of the separate controls required by the device of Topholm, thereby making the device easier to manufacture. The computer readable medium includes sufficient storage capacity as claimed. The stored signals may be repeated as necessary to provide 4 hours of treatment signal.

**Claims 1-8 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Jassim (1988) in view of Sony (TCD-D8 1995)/Girolamo et al (3,023,388, hereinafter Girolamo).

Al-Jassim teaches a device for providing treatment of an auditory system disorder comprising: a computer readable medium for storing a treatment signal, an output for the treatment signal; wherein the device may be used to treat tinnitus or hyperacusis; wherein the treatment signal may be a highly dynamic masking signal whose spectral content and intensity constantly varies over time (as described in paragraph 4 of column 1 of page 27; and in paragraph 1 of the Discussion on page 27). While Al-Jassim teaches that an auditory disorder may be treated by using a Walkman, the specific type of Walkman is not disclosed.

The combination of Sony and Girolamo teaches a device as claimed but does not teach the claimed treatment signal, known as a Walkman, comprising a computer readable medium for storing a desired signal (as described on pages 2, 28-29 and 35), an output for outputting the signal to the auditory system, and a volume-adjusting



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feature (described on pages 18 and 37); wherein the device is capable of being used to treat an auditory system disorder, including tinnitus and hyperacusis, and wherein the patient may reset the volume at any time; wherein the device includes a compliance monitoring device (as described on page 40), a battery (as described on page 25); wherein the battery life may last for at least one week of treatment depending on the length of use of the device during the treatment (as described on page 25); wherein the computer readable medium has a storage capacity sufficient to provide a choice, range, or diversity of treatment signals (as described on pages 2, 28 and 29); wherein the computer readable medium storage capacity is approximately equivalent to 4 hours (as described on page 35); wherein the device further comprises coding of the treatment signal capable of preventing copying and tampering by a user (as described on page 29); wherein the device comprises a data downloading function, performed by a wired interface, capable of downloading logged information (for example: preferred treatment signals) which relate to the patient's use of the device (as described on page 28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a device similar to that of Sony/Girolamo to administer a treatment signal in a method similar to that taught by Al-Jassim to treat an auditory disorder because the Walkman is less expensive than commonly used tinnitus maskers, is readily usable which cuts down on the caregiver's time as well as the user's wait time for receiving treatment, the device is easy to handle and allows the user to choose from a variety of treatment signals (as described in column 1 of page 28 of Al-Jassim).

**Claim 11 is** rejected under 35 U.S.C. 103(a) as being unpatentable over Sony (TCD-D8 1995)/Girolamo et al (3,023,388, hereinafter Girolamo) in view of Wolf et al. (Patent 4254922).

Sony/Girolamo teaches the device of claim 14, comprising a computer readable medium, an output, and a volume-adjusting feature for outputting a treatment signal, as described above, but does not teach a patient identification code.

Wolf et al. teaches a device comprising a computer readable medium and an output wherein the device further comprises a locking mechanism and an identification code (as described in claims 1, 24 and 25 and in lines 16-20 of column 9) (as seen in Figure 17).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a device similar to that of Sony with an identification code similar to that of the device of Wolf et al. in order to identify the owner of said device if lost.

**Claims 27-29, and 31-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zoels et al. (Patent 6047074) in view of Rastatter et al. (Patent 5961443) and Girolamo et al (3,023,388, hereinafter Girolamo).

Zoels et al. teaches a device comprising a signal filtering means configured to generate a treatment signal with peaks and troughs by modifying an input signal and an output for outputting the signal for treatment of an auditory disorder, including tinnitus; wherein the signal filtering means and output are part of a hearing aid (as described in

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the abstract and in lines 36-67 of column 2 and lines 1-16 of column 3). Zoels et al. however, does not expressly teach a hearing aid with a volume-adjusting feature.

Rastatter et al. teaches a hearing aid (10) with a volume adjusting feature (15a) for treatment of an auditory disorder (as seen in Figure 1); wherein the hearing aid further comprises a battery (as described in lines 58-67 of column 4; lines 63-67 of column 8 and lines 1-4 of column 9) and/or a battery pack which supplies power for extended use which could last for a week, depending on the treatment regime, and a separate on/off switch, battery door. The device of Girolamo requires the user to set the volume each time the device is turned on from the off position. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a combined control device for the on/off and volume function that requires the user to set the volume each time the device is turned on as required by the switch taught by Girolamo in place of the separate controls required by the device of Rastatter, thereby making the device easier to manufacture. The computer readable medium includes sufficient storage capacity as claimed. The stored signals may be repeated as necessary to provide 4 hours of treatment signal.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a hearing aid similar to that of Rastatter et al/Girolamo. with a signal filtering means similar to that taught by Zoels et al. to produce an output for treating an auditory disorder because the hearing aid of Rastatter et al/Girolamo. is designed to

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provide a user with a therapeutic signal and the volume adjust allows for increased comfort of the user.

### ***Allowable Subject Matter***

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 9, none of the prior art of record teaches or fairly suggests a device for providing treatment of an auditory system disorder comprising, a computer readable medium, an output for outputting the signal for treating the auditory system disorder, a volume adjusting feature and a safety locking function capable of preventing a patient from using the device if the computer readable medium does not contain the patient's treatment signal.

Claims 14-16 and 18-26 are allowed.

### ***Response to Arguments***

Applicant's arguments set forth in the papers of 7/20/2007 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel G. Gilbert/  
Primary Examiner, Art Unit 3735  
Samuel G. Gilbert  
Primary Examiner  
Art Unit 3735